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PATENTIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: John W. Forsberg, Mark E. Confirmation No. 9349
Schommer, David P.
Olson, William C. Phillips,
Alex C. Toy and Charles
R. Lewis, Jr.
Serial No.: 10/693,005
Filed: October 24, 2003 Customer No.: 28863
Examiner: Christopher A. Flory
Group Art Unit: 3762
Docket No.: 1023-294US01

Title: MEDICAL DEVICE PROGRAMMER WITH INFRARED COMMUNICATION

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We are transmitting herewith the attached correspondence relating to this application:

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DEC - 8 2008**PATENT****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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COMMUNICATION

APPEAL BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
Alexandria, VA 22313-1450

Sir:

This is a brief in support of an appeal from the Office Action mailed on March 21, 2008 finally rejecting claims 1-12, 14-21, and 32, and the Advisory Action mailed on October 1, 2008 reaffirming the rejection of claims 1-12, 14-21, and 32. The period of response for filing this brief runs through December 9, 2008.

On December 3, 2007, Appellant filed a first brief in support of an appeal ("Appeal Brief") and paid a fee of \$510.00 for filing the Appeal Brief. Prosecution was reopened following the filing of the first Appeal Brief. Accordingly, the previously paid Appeal Brief fee may be applied to the present Appeal Brief. Please charge Deposit Account No. 50-1778 in the amount of \$30.00, which is the difference between the increased Appeal Brief fee and the amount previously paid. Please charge any additional fees that may be required or credit any overpayment to Deposit Account No. 50-1778.

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REAL PARTY OF INTEREST

The Real Party of Interest is Medtronic, Inc. of Minneapolis, Minnesota.

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RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences for the above-referenced patent application.

STATUS OF CLAIMS

Claims 1-12, 14-21, and 32 are pending and are the subject of this Appeal. Claim 13 and 22-31 were previously canceled. The pending claims 1-12, 14-21, and 32 are set forth in Appendix A.

Claims 1-12, 14, 15, 17-21, and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows et al. (U.S. Patent No. 6,516,227, hereinafter referred to as Meadows) in view of Whitehurst et al. (U.S. Patent Application Publication No. 2003/0229383, hereinafter referred to as Whitehurst). Claims 16 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows in view of Whitehurst and further in view of Stanton et al. (U.S. Patent No. 6,249,703, hereinafter referred to as Stanton).

STATUS OF AMENDMENTS

An Amendment in response to a final Office Action dated May 3, 2007 was filed on August 3, 2007. An Advisory Action mailed August 23, 2007 indicated that the Amendment filed on August 3, 2007 was deemed not to place the application in condition for allowance, but would be entered for purposes of appeal. The claims have not been amended since the Amendment filed on August 3, 2007.

SUMMARY OF CLAIMED SUBJECT MATTER

In general, the invention relates to a medical device programmer that includes an infrared interface to receive changes to software executed by a processor of the programmer and a controller to control the infrared interface.¹ The controller controls the infrared interface to seek

¹ See, e.g., Appellant's originally-filed disclosure at p. 6, ll. 11-19.

an infrared communication session for a limited period of time following power-up of the programmer,² thereby conserving power.

Independent claim 1 is directed to a medical device programmer³ comprising an infrared interface⁴ to receive changes to software executed by a processor⁵ within the programmer during an infrared communication session⁶, and a controller⁷ to activate the infrared interface to seek an infrared communication session for a finite period of time⁸ in response to power-up⁹ of the programmer. The controller deactivates the infrared interface after the finite period of time if the infrared communication session is not established¹⁰.

Claim 2 depends from claim 1 and specifies that the finite period of time following power-up of the programmer is approximately 5 to 10 seconds.¹¹

Claim 6 specifies that the programmer of claim 1 further includes a software loading port¹² for loading software into memory upon assembly of the programmer, and a housing defining an aperture¹³ that provides access to the software loading port. Dependent claim 8, which depends from claim 6, further recites a plate member¹⁴ placed to cover the loading port. The software loading port that is accessible from outside the programmer housing and the plate member that covers the software loading port advantageously permit the programmer to be programmed as one of the final steps in the manufacturing process.¹⁵ For example, a large number of programmers may be preassembled, placed in storage, if desired, and then programmed for operation with an appropriate type of medical device via loading software via the software loading port.¹⁶ Thereafter, a plate member may be placed to cover the aperture in the housing so that the software loading port is covered.¹⁷

² See, e.g., *id.* at p. 18, ll. 4-6.

³ See, e.g., *id.* at p. 14, ll. 1-3 and programmer 20 in FIG. 1.

⁴ See, e.g., *id.* at p. 18, l. 4 and infrared interface 70 in FIG. 4.

⁵ See, e.g., *id.* at p. 18, ll. 12-16.

⁶ See, e.g., *id.* at p. 18, ll. 6-8.

⁷ See, e.g., *id.* at p. 14, ll. 3-5.

⁸ See, e.g., *id.* at p. 14, ll. 3-5 and p. 18, ll. 8-11.

⁹ See, e.g., *id.* at p. 14, ll. 3-5.

¹⁰ See, e.g., *id.* at p. 18, ll. 13-15.

¹¹ See, e.g., *id.* at p. 18, ll. 4-6.

¹² See, e.g., *id.* at p. 5, ll. 23-29 and loading port 74 in FIG. 5.

¹³ See, e.g., *id.* at p. 17, ll. 18-20 and housing 96 in FIG. 5.

¹⁴ See, e.g., *id.* at p. 17, ll. 17-21 and faceplate 68 in FIG. 5.

¹⁵ See, e.g., *id.* at p. 5, ll. 30-31.

¹⁶ See, e.g., *id.* at p. 6, ll. 1-8.

¹⁷ See, e.g., *id.*

Claim 11 depends from claim 1 and specifies that the programmer includes a first circuit board¹⁸ including telemetry circuitry and a second circuit board¹⁹ including a display and display circuitry. Claim 15 depends from claim 11 and specifies that the programmer includes an internal antenna²⁰ mounted to the first circuit board²¹, where the internal antenna defines an aperture²², and the programmer further includes a battery bay²³ extending at least partially into the aperture²⁴. This arrangement between the battery bay and aperture defined by the antenna may help reduce external magnetic interference to the internal antenna by providing a radio frequency load to the internal antenna, thereby enhancing noise immunity.²⁵

Claim 16 also depends from claim 11 and further recites an external antenna²⁶ coupled to the telemetry circuitry of the first circuit board.²⁷

GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following grounds of rejection to be reviewed on Appeal:

1. Whether claims 1–12, 14, 15, 17–21, and 32 are unpatentable under 35 U.S.C. § 103(a) over Meadows in view of Whitehurst; and
2. Whether claim 16 is unpatentable under 35 U.S.C. § 103(a) over Meadows in view of Whitehurst and further in view of Stanton.

ARGUMENT

Appellant respectfully traverses the current rejection of claims 1–12, 14–21, and 32 advanced by the Examiner, and requests reversal of such rejections by the Board of Patent Appeals based on the arguments below. For each ground of rejection, Appellant respectfully requests separate review of each set of claims argued under separate headings.

¹⁸ See, e.g., antenna circuit board 106 in FIG. 13.

¹⁹ See, e.g., display circuit board 104 in FIG. 13.

²⁰ See, e.g., internal antenna 32 in FIG. 12.

²¹ See, e.g., FIG. 12.

²² See, e.g., aperture 112 in FIG. 12.

²³ See, e.g., battery bay 108 in FIG. 12.

²⁴ See, e.g., Appellant's originally-filed disclosure at p. 23, ll. 21–23.

²⁵ See, e.g., *id.* at p. 23, ll. 22–26.

²⁶ See, e.g., external antenna 34 in FIG. 13.

²⁷ See, e.g., Appellant's originally-filed disclosure at p. 24, ll. 2–3.

First Ground of Rejection Under Appeal

Claims 1–12, 14, 15, 17–21, and 32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows in view of Whitehurst. Appellant respectfully submits that the rejection of claims 1–12, 14, 15, 17–21, and 32 was in error and should be reversed.

In order to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), it is well established that three basic criteria must be met. First, there must be some motivation or apparent reason to modify the reference or combine the reference teachings to arrive at the claimed invention.²⁸ Second, there must be a reasonable expectation of success. Finally, the prior art references when combined must teach or suggest all the claim limitations.²⁹ The Examiner's rejection of claims 1–12, 14, 15, 17–21, and 32 based on Meadows in view of Whitehurst fails to meet these criteria, and, accordingly, the Examiner's rejection of Appellant's claims was improper and should be reversed.

Independent Claim 1

Independent claim 1 recites a medical device programmer comprising an infrared (IR) interface to receive changes to software executed by a processor within the programmer during an IR communication session, and a controller to activate the IR interface to seek an IR communication session for a finite period of time in response to power-up of the programmer, and deactivate the IR interface after the finite period of time if the IR communication session is not established. Thus, according to claim 1, an IR interface seeks a communication session for a limited period of time (i.e., a finite seeking period) and deactivates if the communication session is not established within that limited period of time, rather than indefinitely seeking the communication session during the entire time the programmer is powered on.

In support of the final rejection of claim 1, the Examiner acknowledged that Meadows does not disclose a finite IR communication session seeking period or deactivation of an IR interface after a finite period of time if the communication session is not established.³⁰ According to the Examiner, Whitehurst discloses a finite seeking period in response to power-up and deactivation of an IR interface after a finite period of time following power-up of the programmer if the communication session is not established because Whitehurst discloses an

²⁸ *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007).

²⁹ *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

³⁰ Final Office Action dated March 21, 2008 at p. 5.

implanted device with “a sleep-listen cycle of seeking a communication session . . . with an external programmer . . .”³¹ The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the IR interface of the Meadows medical device programmer with the radiofrequency (RF) sleep-listen cycle of the Whitehurst implanted device in order to minimize power consumption.³²

Appellant respectfully submits that Whitehurst fails to cure the fundamental deficiencies in Meadows identified by the Examiner, and, accordingly, Meadows in view of Whitehurst cannot render Appellant’s independent claim 1 obvious. Furthermore, the Examiner appears to have misinterpreted Meadows, further supporting Appellant’s assertion that the rejection of independent claim 1 based on Meadows in view of Whitehurst was improper and should be reversed.

As an initial matter, it is unclear why one having ordinary skill in the art would have even consulted the Whitehurst reference, which relates to an implanted medical device, to modify Meadows, which relates to an external medical device programmer. Whitehurst describes an implanted device with a RF telemetry system that allows the implanted device to communicate with an external remote device.³³ The RF telemetry system includes an RF telemetry receiver³⁴ that is periodically turned on and off indefinitely (i.e., a “sleep-listen cycle”³⁵), thereby conserving power consumption of the implanted device.³⁶ Thus, Whitehurst describes an implanted device that includes an RF telemetry receiver with an indefinite sleep-listen cycle.

The Examiner proposed modifying the IR interface of an external medical device programmer described by Meadows with the RF telemetry receiver of the Meadows implanted device.³⁷ However, the Examiner failed to provide any rationale for why one of ordinary skill in the art looking to modify an external IR interface as described by Meadows would have looked to the implanted RF telemetry receiver described by Whitehurst. Similarly, the Examiner failed to provide a rationale for why one of ordinary skill in the art looking to modify an external medical device programmer with an IR interface as described by Meadows would have looked to the implanted device described by Whitehurst. To establish obviousness, the Examiner must

³¹ *Id.*

³² *Id.*

³³ Whitehurst at paragraph [0011].

³⁴ *Id.* at paragraph [0030] and implant receiver 52 in FIG. 2.

³⁵ *Id.* at paragraph [0036].

³⁶ *Id.* at paragraphs [0011], [0030], and [0036].

³⁷ Final Office Action dated March 21, 2008 at p. 5.

identify an apparent reason that would have prompted one of ordinary skill in the art to combine the references to arrive at the claimed invention.³⁸ However, in the present case, the Examiner has failed to identify any apparent reason to combine Meadows and Whitehurst in the manner proposed by the Examiner.

Appellant submits that because of the fundamental differences between an external medical device programmer and an implanted medical device and the different design considerations for external programmers and implanted devices, one having ordinary skill in the art would not have looked to the RF telemetry receiver of the Whitehurst implanted device to modify the IR interface of the Meadows external programmer. As one example of the fundamental differences between an external medical device programmer and an implanted medical device, the programmer provides a level of manual control that the implanted device of Whitehurst does not allow. For example, the handheld programmer of Meadows may be turned on and off through direct user activation.³⁹ In contrast, Whitehurst does not describe how the implanted device is powered on. The different degrees of control provided by a programmer compared to an implanted device result in different design criteria, such as design criteria for limiting power consumption. Accordingly, it is unclear why one skilled in the art would have looked to Whitehurst to modify Meadows.

As another example of the fundamental differences between an external medical device programmer and an implanted medical device, the external programmer typically includes an IR interface to communicate with another external device and a separate RF interface to communicate with an implanted device. For example, Meadows discloses that its handheld programmer uses an IR port to communicate with an external computer and RF communication to connect to an implanted device.⁴⁰ On the other hand, an implanted device typically includes an RF interface to communicate with an external device and is typically incapable of communicating with the external device via an IR interface as the device is implanted within the body of the patient. Whitehurst does not indicate that the RF communication techniques described therein apply to IR communication. Thus, even if Meadows was modified in view of

³⁸ *KSR Int'l Co.*, 127 S. Ct. at 1741.

³⁹ Meadows at col. 26, ll. 51–52.

⁴⁰ *Id.* at col. 31, ll. 40–42 and FIG. 7D, which illustrates a separate IrDa module 640 and RF module 650. Meadows states that, “Infrared communications with the [handheld programmer] occur through an IrDa module 640” and “[i]t is through this RF module 650 and related circuitry that the HHP 202 sends and receives RF command signals.” Col. 39, ll. 34–37 and ll. 50–53.

Whitehurst as proposed by the Examiner, the resulting combination would not meet each and every limitation of Appellant's independent claim 1.

Whitehurst relates entirely to an RF communication technique for use between an implanted device and an external remote device, and provides no teachings that are pertinent to communication between two external devices, i.e., lacks any disclosure relating to an IR interface. Thus, combining the teachings of Meadows and Whitehurst would result in an altered RF interface between the handheld programmer and implantable pulse generator described by Meadows. The IR interface between the handheld programmer and the clinician programmer disclosed by Meadows would remain unchanged. Indeed, the resulting modification of Meadows in view of Whitehurst would not result in a programmer that includes an IR interface that is activated to seek an IR communication session for a finite period of time or deactivated after the finite period of time if the communication session is not established, as required by Appellant's claim 1.

Meadows in view of Whitehurst also fails to disclose or suggest a programmer that includes an IR interface that is activated to seek a communication session in response to power-up of the medical device programmer, as required by claim 1. In the final Office Action, the Examiner stated that it is an inherent property of the Meadows handheld programmer that the IR communication session is initiated in response to power-up of the handheld programmer because Meadows discloses that the handheld programmer is "always appropriately synchronized" with the clinician programmer, and cited column 36, lines 24–28 of Meadows.⁴¹ Appellant respectfully disagrees with the Examiner's analysis of Meadows.

When read in context of the surrounding disclosure, at column 36, lines 24–28, Meadows discusses a handheld programmer that can be used to program an implanted medical device. Meadows states that "all programming systems (those used within the handheld programmer 202 and within the clinician's programmer 204) are always appropriately synchronized . . . so that any changes from one are reflected in the other."⁴² Meadows is absolutely silent as to when the IR interface is activated or when the handheld programmer is synchronized with the clinician programmer. Thus, it is unclear how this limited disclosure in Meadows would have suggested an IR interface that is activated in response to power-up of the handheld programmer, as the

⁴¹ Final Office Action dated March 21, 2008 at p. 6.

⁴² Meadows at col. 36, ll. 24–28.

Examiner appears to find. Nothing in Meadows indicates that the handheld programmer is automatically synchronized with the clinician programmer after power-up of the handheld programmer.

To support a finding of an inherent disclosure in Meadows, the Examiner must provide a basis in fact or technical reasoning to support that the allegedly inherent characteristic necessarily flows from the teachings of Meadows.⁴³ Meadows fails to provide any basis for concluding that the handheld programmer described therein includes an IR interface that is necessarily activated upon power-up of the handheld programmer. For example, based on the limited disclosure provided by Meadows relating to the IR interface, it is possible that the IR interface of the handheld programmer is purposefully activated by a user at any time, e.g., when the user wants to connect to a clinician programmer, rather than automatically activated in response to power-up.

As one example of the many possibilities in view of the Meadows disclosure, it may be possible that the IR interface of the Meadows handheld programmer is activated upon connection of the clinician programmer to allow proper synchronization with another programmer, which does not necessarily occur at power-up. Meadows discloses that the handheld programmer is selectively connected to a clinician programmer through an IR serial port using an IR cable extension.⁴⁴ Because the handheld programmer may be selectively connected to the clinician programmer,⁴⁵ the handheld programmer does not necessarily automatically seek a communication session with the clinician programmer in response to power up.

Meadows discloses that the handheld programmer may directly communicate with an implantable pulse generator without the presence of the clinician programmer,⁴⁶ and, accordingly, there is absolutely no basis for stating that the Meadows handheld programmer must necessarily activate its IR interface upon power-up. Rather, because the IR interface is not used at all times, but is selectively activated, and Meadows does not disclose that the IR interface is activated in response to follow-up, it follows that the Meadows handheld programmer does not necessarily activate the IR interface in response to power-up of the programmer. Thus, the

⁴³ *Ex parte Levy*, 17 USPQ.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)

⁴⁴ Meadows at col. 31, ll. 41-43.

⁴⁵ See, e.g., claim 1 of Meadows.

⁴⁶ Meadows at col. 36, ll. 10-16.

Examiner's finding of an inherent disclosure in Meadows of the activation of an IR interface in response to power-up is improper.

The Examiner also provided an alternative rationale for supporting the rejection of claim 1. The Examiner stated that "it would be obvious to start the IR seek session on power-up of the device since it is well-known in the art to provide power-up telemetry sessions in devices that have programmers to verify and/or update protocol and operational data within the system."⁴⁷ However, the Examiner did not offer any support found within the prior art for this alternative reasoning that activating an IR interface to seek an IR communication session for a finite period of time in response to power-up is known. Accordingly, the rejection of claim 1 on this alternative ground was improper.

As yet another alternative rationale, the Examiner found that the disclosure of an interrogation of an implantable pulse generator in response to the activation of a hidden physician screen included on the handheld programmer by Meadows constitutes seeking an IR communication session for a finite period of time in response to power-up of the programmer.⁴⁸ The Examiner appeared to improperly relate the disclosure in Meadows relating to an RF communication session between a programmer and an implanted device to the IR communication session recited in claim 1. The IR interface and RF telemetry circuitry of the Meadows programmer are two completely separate interfaces.⁴⁹ The IR interface supports communication between the external programmer and another external device. The RF interface supports communication between the external programmer and an implanted device. Yet, in the final Office Action, the Examiner combined the description of the IR interface and RF interface to reject Appellant's claim 1 and impermissibly conclude that Meadows discloses a medical device programmer that seeks an IR communication session in response to power-up of the programmer.

Furthermore, even if the disclosure relating to the RF interface of the Meadows programmer were relevant to the IR interface of Appellant's claim 1, which Appellant disputes, activation of a specific feature of the handheld programmer, i.e., the hidden physician screen, does not amount to power-up of the programmer itself, as the Examiner appears to be concluding. Meadows discloses that access to the hidden physician screen is made available

⁴⁷ Final Office Action dated March 21, 2008 at p. 7.

⁴⁸ *Id.* at p. 12.

⁴⁹ *See, e.g.,* Meadows at col. 31, ll. 41-45.

through a specified coded button combination. The example Meadows provides is “pressing the IPG button 242 and the up/down buttons 244 and 245 simultaneously, followed by pressing a set sequence of the other buttons, e.g., pressing the SEL button 243 once, followed by the pressing the down button 245 twice.”⁵⁰ In addition, Meadows specifically discloses that its handheld programmer is powered-on by simply pressing any button, not by activating a physician screen.⁵¹ The physician screen is activated (and hence the subsequent interrogation of the implantable pulse generator occurs) only after a specified combination of buttons are pressed, rather than upon power-up. Thus, the Examiner’s third basis for finding that Meadows discloses an IR interface that is activated in response to power-up of the programmer is incorrect and finds no basis within the cited art.

Whitehurst also fails to disclose an IR interface that is activated in response to power-up of a programmer. Even if the disclosure relating to the Whitehurst RF telemetry receiver were relevant to the IR interface recited in claim 1, which Appellant disputes, Whitehurst completely fails to provide any disclosure relating to activation of its RF telemetry receiver. It is unclear why Whitehurst would disclose an RF receiver that is only activated for a limited period of time following power-up of the implanted device. If this were the case, the Whitehurst implanted device would need to power-off and subsequently power-up each time communication with an external device was desired. This seems to contradict the Whitehurst disclosure, which is concerned with periodically activating an RF telemetry system “so as to allow a reasonably prompt response of the implant to a request for a communication session by the external device.”⁵² It is unclear how the implanted device would respond to a request for a communication session in a “reasonably prompt” manner if the implanted device only activated its RF telemetry system in response to power-up of the implanted device. Whitehurst does not even indicate that the implanted device may be turned on and off, and even suggests that turning the implanted device off is undesirable.⁵³

The Whitehurst implanted device seeks the RF telemetry session with an external programmer in order to receive programming commands.⁵⁴ It seems that these programming commands would be received throughout an on-state of the implanted device, rather than

⁵⁰ *Id.* at col. 38, ll. 22–32.

⁵¹ *Id.* at col. 26, ll. 51–52.

⁵² Whitehurst at paragraph [0011].

⁵³ *See, e.g., id.* at paragraph [0048].

⁵⁴ *Id.* at paragraph [0046].

following a finite period of time following power-up of the implanted device. Whitehurst does not provide any disclosure relating to when the programming commands are received relative to power-up of the implanted device. In contrast, Appellant's claim 1 requires the IR interface of the programmer to only be activated for a limited period of time following power-up of the programmer.

By disclosing an implanted device and the undesirability of the implanted device expending its power source and inadvertently turning off, Whitehurst appears to teach away from activating an IR interface in response to power-up, as required by Appellant's claim 1. Moreover, as described above, the disclosure relating to an RF interface of the Whitehurst implanted device is not pertinent to an IR interface of an external programmer because the IR interface and RF interface rely on two separate communication techniques and considerations. As evidenced by Meadows and Whitehurst, an implanted device, as taught by Whitehurst, typically does not communicate with an external device via IR communication techniques, but rather, communicates with an external device via RF communication techniques. As further evidenced by Meadows and Whitehurst, it is well-known that an RF interface is separate and distinct from IR communication techniques used by external devices to communicate with other external devices.⁵⁵

Neither Meadows nor Whitehurst disclose or suggest a controller that activates an IR interface to seek an IR communication session for a finite period of time in response to power-up of the programmer, and deactivate the IR interface after the finite period of time if the IR communication session is not established. The Examiner acknowledged that Meadows lacks such a disclosure.⁵⁶ However, the Examiner found that the sleep-listen cycle of the RF telemetry receiver of the Whitehurst implanted device amounts to a disclosure of a controller that activates an IR interface to seek a communication session for a finite period of time in response to power-up and deactivates the IR interface after the finite period of time if the IR communication session is not established.⁵⁷

⁵⁵ See, e.g., Meadows at col. 31, ll. 40-42, and FIG. 7D, which illustrates a separate IrDa module 640 and RF module 650. Meadows states that, "[i]nfrared communications with the [handheld programmer] occur through an IrDa module 640" and "[i]t is through this RF module 650 and related circuitry that the HHP 202 sends and receives RF command signals." Col. 39, ll. 34-37 and ll. 50-53.

⁵⁶ Final Office Action dated March 21, 2008 at p. 5.

⁵⁷ Final Office Action dated March 21, 2008 at p. 5.

As previously established, Whitehurst describes an RF communication technique for use between an implanted device and an external remote device. The RF telemetry receiver disclosed by Whitehurst operates under an indefinite sleep-listen cycle that is not related to power-up of the programmer.⁵⁸ The Examiner proposed modifying the IR interface of the Meadows programmer with the RF telemetry receiver of the Whitehurst implanted device. Combining the teachings of Meadows and Whitehurst, as proposed by the Examiner, would result in an altered RF interface between the handheld programmer and implantable pulse generator. However, claim 1 recites an external IR interface. Modifying Meadows in view of Whitehurst as proposed by the Examiner would not change the IR interface between the handheld programmer and the clinician programmer. Thus, the RF teachings of Whitehurst and the IR disclosure of Meadows are plainly incongruent, at least insofar as the limitations of claim 1 are concerned.

Claim 1 must be read as a whole. Claim 1 does not recite a controller that activates an IR interface and deactivates the IR interface in an endless cycle, as the RF telemetry receiver in Whitehurst appears to do. Rather, claim 1 specifically requires that the controller activates the IR interface in response to power-up of the programmer, and deactivates the IR interface after a finite period of time following the power-up of the programmer if the communication session is not established. The endless sleep-listen cycle disclosed by Whitehurst, on the other hand, is activated based on defined time periods that are unrelated to a power-up of the implanted device, and, therefore, modifying Meadows in view of Whitehurst cannot render Appellant's claim 1 obvious, even if operation of the RF interface of Whitehurst were relevant to the claimed IR interface. As described above, Whitehurst does not disclose or even suggest how its implanted device may be powered on or off. Furthermore, the implanted device taught by Whitehurst does not appear to allow a user to control when the telemetry interface of the implanted medical device is activated.

In addition to failing to meet the burden of establishing a *prima facie* case of obviousness, the Examiner appears to have incorrectly interpreted Appellant's claim 1. In the final Office Action, the Examiner incorrectly characterized Appellant's claim 1 as requiring a finite communication session. More specifically, the Examiner addressed the limitation that "the

⁵⁸ Whitehurst at Abstract and paragraph [0036].

infrared communication session is initiated for a finite amount of time.”⁵⁹ However, Appellant’s claim 1 requires that the IR interface seeks an IR communication session for a finite period of time.

The Examiner alleged that Meadows discloses that a telecommunicative link is established each time a stimulus parameter is changed or a charging session is initiated.⁶⁰ The Examiner also characterized turning off the handheld programmer after a period of disuse as a terminus of a finite IR communication session. However, Appellant’s claim 1 is not directed toward finite communication sessions but rather a finite seeking period to initiate a communication session. It seems that the Examiner has confused a finite communication period, per Meadows, with a finite seeking period as claimed. Even if the Meadows handheld programmer establishes multiple IR communication sessions with a clinician programmer, the IR interface of the handheld programmer may be continuously activated to listen for communication from (e.g., seek a communication session with) the clinician programmer.

The Meadows handheld programmer does not include a controller to deactivate an IR interface if a communication session is not established after a finite period of time, as required by Appellant’s claim 1. On the contrary, Meadows discloses multiple communication sessions having finite periods. The Examiner also stated that “since Meadows discloses multiple subsequent communication sessions, it is indeed inherent that not only is the duration of each session finite, but the duration of time between communications (i.e. the seeking period) is finite.”⁶¹ Yet, this statement does not reflect a proper understanding of the actual limitations set forth in Appellant’s claims.

Appellant disagrees with the Examiner’s characterization of the duration of time between each telecommunicative link as a finite period of time for seeking an IR communication session. The finite period of time set forth in claim 1 does not refer to the period of time between communication sessions, but rather the seeking of a communication session upon activation of the IR interface. Even if multiple communication sessions are established in the Meadows system, the time between each of the sessions is not the pertinent issue. Again, the finite length limitation in claim 1 pertains to the limited listening period during which the IR interface seeks a communication session.

⁵⁹ Final Office Action dated March 21, 2008 at p. 5.

⁶⁰ *Id.* at pp. 5 and 6.

⁶¹ *Id.* at p. 12.

With respect to the time periods between communication sessions, which the Examiner has characterized as seeking periods,⁶² each of these time periods is terminated when a communication session is established, rather than if the communication session is *not* established. In fact, because Meadows teaches a system in which the handheld programmer and clinician's programmer, which communicate via IR interfaces, are always properly synchronized,⁶³ an IR communication session is likely sought until the communication session is established. This directly contradicts the requirements of Appellant's claim 1.

For at least these reasons, Meadows in view of Whitehurst fails to disclose or suggest each and every element of independent claim 1, and the rejection of claim 1 should be reversed.

Claims 2–12, 14, 15, 17–21, and 32 depend from claim 1, and are patentable over Meadows in view of Whitehurst for at least the reasons discussed above with respect to claim 1. Meadows in view of Whitehurst also fails to disclose or suggest the further requirements recited in dependent claims 2–12, 14, 15, 17–21, and 32. Appellant argues some of the dependent claims under separate headings below.

Claim 2

Meadows in view of Whitehurst fails to disclose or suggest the limitations of Appellant's claim 2, which recites a finite time period of approximately 5 to 10 seconds following power-up to seek an IR communication session. The Examiner cited Whitehurst as teaching a finite seeking period and deactivation of the IR interface after a finite period of time if the communication session is not established.⁶⁴ However, Whitehurst describes a seeking period of 10 to 200 milliseconds, which is outside of the range of 5 to 10 seconds specified by claim 2.⁶⁵ Whitehurst teaches that, "the period of activation [of the RF telemetry system is] . . . sufficiently short so as to allow a reasonably prompt response of the implant . . ."⁶⁶ Given the vast difference between a 10 to 200 millisecond time range and a 5 to 10 second time range for seeking a communication session, Whitehurst cannot disclose or even suggest a 5 to 10 second listening period for its RF telemetry system, particularly in light of the power limitations⁶⁷ of an implanted

⁶² *Id.* at p. 12.

⁶³ Meadows at col. 17, ll. 61–65 and col. 36, ll. 24–28.

⁶⁴ Final Office Action dated March 21, 2008 at p. 5.

⁶⁵ Whitehurst at paragraph [0037].

⁶⁶ *Id.* at paragraph [0011].

⁶⁷ *Id.* at paragraph [0026].

device. Furthermore, nothing in the cited references provides a teaching or motivation for providing an IR interface that seeks a communication session for a 5 to 10 second period of time.

In support of the rejection of claim 2, the Examiner cited paragraph 40 of Whitehurst as teaching a seeking time-out period of 10 seconds. However, the timeout period described by this passage of Whitehurst refers to a period of time elapsed after a command is received, rather than a finite period of time following power up of the device. After the timeout period, the implant switches from a receive mode with a 100 millisecond seeking period to a sleep-listen cycle with a shorter (e.g., 20 millisecond) seeking period.

Additionally, the Examiner reasoned that claim 2 is obvious because if the Meadows system remains in use for an hour or is always on, the IR interface is active for 5–10 seconds by nature of being on for longer than that.⁶⁸ The Office Action also reasoned that if the patient or clinician using the device powers down after 8 seconds, then the IR interface has been active for 8 seconds, which satisfies the requirements of claim 2.⁶⁹ However, Appellant's claim 2 requires a controller that deactivates the IR interface after approximately 5 to 10 seconds if the IR communication session is not established. The approximately 5 to 10 second period of time recited in claim 2 refers to a listening period for seeking a communication session, rather than the duration of the communication session itself. Therefore, an IR interface that is on for longer than 5–10 seconds does not meet the requirements of claim 2. Additionally, if a programmer is turned off after 8 seconds, the IR interface is not necessarily seeking the communication session during that 8 seconds. Even if the IR interface seeks the communication session during the 8 seconds the Meadows device is used, an assertion with which Appellant disagrees, the IR interface is turned off regardless of whether or not a communication session is established and, therefore, fails to meet the requirements of claim 2.

Claims 6–9

Meadows in view of Whitehurst also fails to disclose or suggest the limitations of Appellant's claim 6, which recites a programmer including a software loading port for loading the software upon assembly of the programmer, and a housing defining an aperture that provides access to the software loading port. Claim 7 depends from claim 6 and specifies that the

⁶⁸ Final Office Action dated March 21, 2008 at p. 8.

⁶⁹ *Id.*

software loading port includes a JTAG interface. Meadows in view of Whitehurst also fail to disclose or suggest a plate member placed to cover the loading port, as further required by claim 8 or a plate member printed with identifying information, as recited by claim 9.

In support of the rejection of claims 6 and 8, the Examiner stated that any electronic device comprising a housing of more than one part and containing software loaded on a memory inherently comprises a software loading port, where the port is consider to be the open portion of the housing in which the software-loaded circuitry is being inserted or affixed, and the other portion of the housing is considered to be the plate member covering the loading port.⁷⁰

However, claim 6 recites a software loading port that is separate from an aperture in a housing that provides access to the software loading port. Accordingly, contrary to the Examiner's assertions, a software loading port is not the opening in a housing through which software-loaded circuitry is inserted into the housing. Instead, as fully supported by Appellant's specification, such as at paragraphs [0024] and [0110], the software loading port is an interface, such as an interface configured to engage with a programming head,⁷¹ accessible from outside the housing, to load software into memory. The housing of the programmer defines an aperture through which the software loading port, i.e., the interface, is accessible upon assembly of the programmer. "Any electronic device" does not include a housing defining an aperture that provides access to a software loading port. Furthermore, the Examiner has not cited any references to support the finding that Appellant's claim 6 would have been obvious.

As described in Appellant's originally filed disclosure, it may be advantageous for a programmer to include a software loading port for loading software upon assembly of the programmer. For example, a plurality of generic programmers having common hardware components may be pre-manufactured and stored, and when a specific type of programmer is ordered, one of the generic programmers may be loaded with the appropriate software through the exposed loading port as one of the final steps in the manufacturing process.⁷² The plate member is subsequently placed on the housing to cover the loading port, thereby blocking access to the loading port.⁷³

⁷⁰ *Id.* at p. 7.

⁷¹ Appellant's originally-filed disclosure at p. 6, ll. 3-5.

⁷² *Id.* at p. 5, ll. 30-31, p. 6, ll. 1-8, and p. 13, ll. 9-14.

⁷³ *Id.* at p. 5, ll. 27-30.

The Examiner reasoned that the “other portion of the housing” is considered to be a plate member. However, the Office Action offered no support for the conclusion that the Meadows programmer even includes two housing portions, or that one housing portion necessarily covers an open portion of another housing portion through which “software-loaded circuitry is being inserted or affixed.” Moreover, such an interpretation of Applicant’s claimed software loading port is unreasonable. Mcadows does not disclose any of the elements of Appellant’s claims 6–9.

Claims 11, 12, 14, and 17

Appellant’s claim 11 recites a first circuit board including telemetry circuitry and a second circuit board including a display and display circuitry. According to the Examiner, “It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Meadows et al. with the two circuit boards as an obvious expedient to simplifying the manufacturing process and for the purpose of making the device of a size similar to other hand held devices that use a hinged two board design, such as cellular phones.”⁷⁴ However, even if it would have been obvious to use two circuit boards to construct a programmer in order to simplify a manufacturing process, which Appellant disputes, the Examiner has not cited any prior art that discloses a programmer that includes telemetry circuitry and display and display circuitry on separate circuit boards, as recited by claim 11. The Examiner appears to have disregarded these requirements of claim 11.

None of the cited references disclose or suggest such a configuration of two circuit boards. As disclosed by Appellant’s originally-filed disclosure, the separation distance between the circuit boards may serve to reduce the effects of electrical and electromagnetic interference caused by the display on signals transmitted and received by the internal antenna.⁷⁵ In addition, the placement of the antenna and display electronics on different circuit boards may reduce electrical and electromagnetic interference.⁷⁶

In the Response to Arguments presented in the final Office Action, the Examiner reasoned that Lee et al. (U.S. Patent No. 6,614,664, hereinafter referred to as Lee) provides support for the Examiner’s assertion that a two circuit board design is an “obvious expedient to the design process” because Lee provides support for the assertion that “[l]ess noise will arise

⁷⁴ Final Office Action dated March 21, 2008 at p. 9.

⁷⁵ Appellant’s originally-filed disclosure at p. 25, ll. 3–5.

⁷⁶ *Id.* at p. 25, ll. 5–7.

between two components the further apart they are placed . . . ”⁷⁷ However, Lee fails to disclose a device that includes a first circuit board including telemetry circuitry and a second circuit board including display and display circuitry, as recited by Appellant’s claim 11. Even in view of Lee, one skilled in the art would not have arrived at the invention of Appellant’s claim 11 based on the cited references. No disclosure within Lee or the other cited references even suggests a programmer including a first circuit board including telemetry circuitry and a second circuit board including a display and display circuitry.

Consistent with the Federal Circuit’s recent decision in *KSR International Co. v. Teleflex, Inc.*, the Federal Circuit has stated that there must be “some rationale, articulation, or reasoned basis” to support the legal conclusion of obviousness.”⁷⁸ The reason for modification need not conform to the particular motivation or objective of the patent applicant.⁷⁹ However, there still must be some need or problem known in the art that would provide a reason for combining elements in the manner claimed.⁸⁰ Not only has the Examiner failed to demonstrate that each and every element of claim 11 is found within the prior art, the Examiner has failed to provide a reason for placing the telemetry circuitry and display and display circuitry on separate circuit boards.

Claims 12, 14, and 17 depend from claim 11 and are also allowable over Meadows in view of Whitehurst for at least the reasons discussed with respect to claim 11.

Claim 15

Claim 15 recites a programmer including an internal antenna defining an aperture and a battery bay extending at least partially into the aperture. The Examiner stated that it would have been an obvious matter of design choice to one of ordinary skill in the art to modify the system as taught by Meadows by extending the battery bay into the antenna aperture.⁸¹ The Office Action referred to FIG. 25 of Causey et al. (U.S. Patent Application Publication No. 2002/0002326, hereinafter referred to as Causey) and FIGS. 1A and 1B of Malek (U.S. Patent Application Publication No. 2003/0177031) as teaching an internal antenna defining an aperture

⁷⁷ Final Office Action dated March 21, 2008 at p. 13.

⁷⁸ *Alza Corp. v. Mylan Labs.*, 80 USPQ.2d 1001, 1005 (Fed. Cir. 2006) (citing *In re Kahn*, 78 USPQ.2d 1329 (Fed. Cir. 2006)).

⁷⁹ *KSR Int’l Co.*, 127 S. Ct. at 1742.

⁸⁰ *Id.*

⁸¹ Final Office Action dated March 21, 2008 at p. 13.

and a battery bay extending at least partially into the aperture.⁸² However, FIG. 25 of Causey does not illustrate an internal antenna or a battery bay, and certainly does not show a battery bay extending at least partially into an aperture defined by an internal antenna. FIGS. 1A and 1B of Malek also fail to show the limitations of Appellant's claim 15. Malek illustrates clinician's programmer 102 including remote telemetry unit 240 (FIG. 2A) that fits into an aperture on the dorsal side of clinician's programmer 102⁸³ and generally includes a telemetry coil, receiver, transmitter, and telemetry processor. Notably missing from FIGS. 1A and 1B are an internal antenna or a battery bay. The cited figures do not illustrate the limitations of claim 15 and, therefore, fail to disclose or suggest each and every element of claim 15.

Additionally, the Examiner stated that "[i]t would have been an obvious matter of design choice . . . to modify the system as taught by Meadows et al. by extending the battery bay into the antenna aperture, because [Appellant] has not disclosed that such a positioning provides an advantage, is used for a particular purpose, or solves a stated problem."⁸⁴ Even if it were pertinent to the issue of obviousness, it appears that the Examiner has overlooked page 23, lines 8-11 of Appellant's disclosure, which states positioning of a battery bay to extend at least partially into an aperture defined by the internal antenna can reduce external magnetic interference to the internal antenna by providing an RF load to the internal antenna, enhancing noise immunity. The Examiner has not cited any references that teach or suggest the programmer recited in Appellant's claim 15. The reliance on "design choice" without further support found within a prior art reference is improper, and the rejection of claim 15 should be withdrawn.

The Examiner may not merely rely on an assertion of design choice to reject claim 15 in view of Meadows. The Examiner must still identify a reason or a motivation for a worker in the art, without the benefit of Appellant's specification, to make the necessary changes.⁸⁵ Just as with claim 11, not only has the Examiner failed to demonstrate that each and every element of claim 15 is found within the prior art, the Examiner has failed to provide a reason for arriving at the invention of Appellant's claim 15.

⁸² *Id.* at p. 11.

⁸³ Malek at paragraph [0023].

⁸⁴ Final Office Action dated March 21, 2008 at p. 9.

⁸⁵ See MPEP 2144.04(VI)(C).

For at least these reasons, the Examiner's rejection of claims 1-12, 14, 15, 17-21, and 32 was improper and should be reversed.

Second Ground of Rejection Under Appeal

Claim 16 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Meadows in view of Whitehurst and further in view of Stanton. Claim 16 depends from claim 11, and as discussed above with respect to claim 11, the cited references do not disclose or suggest a programmer including a first circuit board including telemetry circuitry and a second circuit board including a display and display circuitry. Claim 16 recites an external antenna coupled to the telemetry circuitry of the first circuit board. Neither Meadows nor Whitehurst nor Stanton discloses or suggests a programmer including two circuit boards, whereby an external antenna is coupled to the first circuit board and a display and display circuitry are included on the second circuit board. In the final Office Action, the Examiner failed to address how the prior art discloses a programmer including separate circuit boards for telemetry circuitry and display circuitry. For at least these reasons, the Examiner has failed to establish a *prima facie* case for obviousness of Appellant's claim 16 under 35 U.S.C. § 103(a). Reversal of this rejection is respectfully requested.

CONCLUSION

The Examiner has failed to meet the burden of establishing a *prima facie* case of anticipation or obviousness with respect to claims 1-12, 14-21, and 32. In view of Appellant's arguments, the final rejection of claims 1-12, 14-21, and 32 is improper and should be reversed, and all of the pending claims should be allowed. Appellant respectfully requests separate review by the Board for each of the grounds of rejection addressed above under separate headings.

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APPENDIX A

THE CLAIMS ON APPEAL

Claim 1: A medical device programmer comprising:

an infrared interface to receive changes to software executed by a processor within the programmer during an infrared communication session; and

a controller to activate the infrared interface to seek an infrared communication session for a finite period of time in response to power-up of the programmer, and deactivate the infrared interface after the finite period of time if the infrared communication session is not established.

Claim 2: The programmer of claim 1, wherein the finite time period time is approximately 5 to 10 seconds following power-up.

Claim 3: The programmer of claim 1, wherein the software changes comprise changes to an operating system of the programmer.

Claim 4: The programmer of claim 1, wherein the software changes comprise changes to medical device programs.

Claim 5: The programmer of claim 1, further comprising a processor to execute instructions specified by the software changes.

Claim 6: The programmer of claim 1, further comprising a software loading port for loading the software into memory upon assembly of the programmer and a housing defining an aperture that provides access to the software loading port.

Claim 7: The programmer of claim 6, wherein the software loading port includes a JTAG interface.

Claim 8: The programmer of claim 6, further comprising a plate member placed to cover the loading port.

Claim 9: The programmer of claim 8, wherein the plate member is printed with identifying information.

Claim 10: The programmer of claim 1, wherein the software includes instructions to implement an embedded operating system within the programmer.

Claim 11: The programmer of claim 1, further comprising:

a first circuit board within a programmer housing, the first circuit board including telemetry circuitry, wherein the telemetry circuit is coupled to an antenna; and

a second circuit board within the programmer housing, the second circuit board including a display and display circuitry.

Claim 12: The programmer of claim 11, wherein the second circuit board includes control circuitry to control the display and the telemetry circuit, the programmer further comprising an electrical interface between the first and second circuit boards.

Claim 14: The programmer of claim 11, further comprising an internal antenna mounted to the first circuit board on a side of the first circuit board facing away from the second circuit board to reduce electromagnetic interference during telemetry using the internal antenna.

Claim 15: The programmer of claim 14, wherein the internal antenna defines an aperture, the programmer further comprising a battery bay extending at least partially into the aperture.

Claim 16: The programmer of claim 11, further comprising an external antenna coupled to the telemetry circuitry via a cable.

Claim 17: The programmer of claim 11, wherein the display is a liquid crystal display.

Claim 18: The programmer of claim 1, wherein the infrared interface is positioned on a lower side surface of a housing associated with the programmer.

Claim 19: The programmer of claim 1, wherein the infrared interface is an Infrared Data Association (IRDA) interface.

Claim 20: The programmer of claim 1, wherein the finite period of time is less than or equal to approximately 10 seconds following power-up.

Claim 21: The programmer of claim 1, wherein the medical device programmer is a programmer for an implantable neurostimulator.

Claim 32: The programmer of claim 1, wherein the controller deactivates the infrared interface after the finite period of time if the infrared interface does not detect an external infrared interface to establish the communication session.

APPENDIX B
EVIDENCE

None.

APPENDIX C
RELATED PROCEEDINGS

None.